June 3, 2025

Austin Medical Ventures, Inc.
℅ John J. Smith
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K250141
Trade/Device Name: Synthecure Synthetic Calcium Sulfate
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV

Dear John J. Smith:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 16, 2025. Specifically, FDA is updating this substantial equivalence (SE) letter as an administrative correction to include the correct device description included within the 510(k) Summary.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jesse Muir, Ph.D., OHT6: Office of Orthopedic Devices, (240) 402-6679, Jesse.Muir@fda.hhs.gov.

Sincerely,

JESSE MUIR -S
Digitally signed by JESSE MUIR -S
Date: 2025.06.03 14:21:59 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

May 16, 2025

Austin Medical Ventures, Inc.
% John J. Smith
Partner
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555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K250141
Trade/Device Name: Synthecure Synthetic Calcium Sulfate
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: January 17, 2025
Received: April 17, 2025

Dear John J. Smith:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2025.05.16 14:23:08 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250141

Device Name

Synthecure Synthetic Calcium Sulfate

Indications for Use *(Describe)*

Synthecure Synthetic Calcium Sulfate is an implant intended to fill bony voids or gaps of the skeletal system (i.e. extremities and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Synthecure Synthetic Calcium Sulfate resorbs and is replaced with bone during the healing process.

Synthecure is provided sterile for single use only. Synthecure is biodegradable and biocompatible and may be used at an infected site.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary
K250141

DATE PREPARED
May 16, 2025

MANUFACTURER AND 510(k) OWNER
Austin Medical Ventures, Inc.
3012 Centre Oak Way, Suite 102, Germantown, TN 38138
Ph: (901) 748-2581
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Allison Komiyama, Ph.D., RAC
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aharalambous@rqmplus.com

DEVICE INFORMATION

Proprietary Name/Trade Name:	Synthecure Synthetic Calcium Sulfate
Common Name:	Resorbable Calcium Sulfate Bone Void Filler
Regulation Number:	21 CFR 888.3045
Class:	Class II
Product Code:	MQV
Review Panel:	Orthopedic

PREDICATE DEVICE IDENTIFICATION
The Synthecure Synthetic Calcium Sulfate is substantially equivalent to the following predicates:

510(k) Number	Predicate Device Name / Manufacturer	Predicate/Reference
K141830	Stimulan Kit, Stimulan Rapid Cure / Biocomposites Ltd.	Predicate
K010532	Osteoset BVF Kit / Wright Medical Technology, Inc.	Reference

DEVICE DESCRIPTION
Synthecure Synthetic Calcium Sulfate is provided sterile for single patient use. Synthecure Synthetic Calcium Sulfate contains calcium sulfate powder and mixing solution in premeasured quantities so that when mixed together in a sterile mixing bowl, the resultant paste is to be digitally packed into open bone void/gap to set in situ or placed into the mold provided where the mixture sets to form beads. The biodegradable, radiopaque beads are resorbed in approximately 30-60 days when used in accordance with the device labeling. Synthecure Synthetic Calcium Sulfate is manufactured from synthetic implant grade calcium sulfate that resorbs and is replaced

with bone during the healing process. Also, as the bone void filler beads are biodegradable and biocompatible, they may be used at an infected site.

INDICATIONS FOR USE

Synthecure Synthetic Calcium Sulfate is an implant intended to fill bony voids or gaps of the skeletal system (i.e. extremities and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Synthecure Synthetic Calcium Sulfate resorbs and is replaced with bone during the healing process.

Synthecure is provided sterile for single use only. Synthecure is biodegradable and biocompatible and may be used at an infected site.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Austin Medical Ventures, Inc. believes that the Synthecure Synthetic Calcium Sulfate is substantially equivalent to the predicate devices based on the information summarized here:

Synthecure Synthetic Calcium Sulfate is identical in function and intended use to the predicate device. The subject and predicate devices are intended to be implanted into defects not intrinsic to the structural stability of the skeletal system. Additionally, the subject device has a similar design and uses similar materials to the predicate. The subject device and the predicate device are presented as a powder, manufactured from medical grade calcium sulfate, and a mixing solution which, when mixed, form a paste which may be digitally implanted or applied to a mold provided to produce beads. Both are biocompatible and may be implanted at an infected site which resorbs and is replaced by bone during the healing process. These technological characteristics have undergone testing to ensure the device is as safe and effective as the predicates.

SUMMARY OF NON-CLINICAL TESTING

Austin Medical Ventures, Inc. has conducted testing per FDA Guidance *Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device* (*issued on June 2, 2003)*. The following tests were performed to demonstrate safety based on current industry standards:

Performance Category	Testing
Sterilization Validation	Sterilization validation has been completed on the worst-case construct to an SAL of $1x10^{-6}$.
Bacterial Endotoxin Testing	Testing is performed according to ANSI/AAMI ST72:2011, *Bacterial endotoxins – Test methods, routine monitoring and alternatives to batch testing*.
Packaging Validation	Packaging performance validation, in accordance with ISO 11607-1:2019 and ISO 11607-2:2019, was performed on the final packaging and sterilized device.

Biocompatibility	A biological safety evaluation has been completed for Synthecure according to ISO 10993-1 requirements and FDA Guidance Document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (issued on September 8, 2023)*. All materials contained in the proposed Synthecure have been evaluated in accordance with recognized standards and are characterized as being biocompatible.
Performance Testing - Bench	The chemical composition and physical properties of the subject and predicate devices were evaluated and demonstrated to be equivalent. Additionally, work and setting time tests were conducted on real-time aged samples to support that the device maintains its performance after aging.
Performance Testing - Animal	An implantation study was conducted using New Zealand White Rabbits with study endpoints at 3, 6, and 12 weeks.

The results of these tests indicate that the Synthecure Synthetic Calcium Sulfate is substantially equivalent to the predicate devices.

CONCLUSION

Based on the testing performed, including sterilization validation, packaging validation, biocompatibility, bench testing and an animal study, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed Synthecure Synthetic Calcium Sulfate are assessed to be substantially equivalent to the predicate devices.